REMARKS

This Amendment is submitted in reply to the non-final Office Action mailed on June 24, 2010. No fees are due herewith this Amendment. The Commissioner is hereby authorized to charge any fees that may be required or credit any overpayment to Deposit Account No. 02-1818. If such a withdrawal is made, please indicate the Attorney Docket No. 3714652-504 on the account statement.

Claims 1, 3 and 5-14 are pending in the application. Claims 2 and 4 were previously canceled. In the Office Action, Claims 1, 3 and 5-14 are rejected under 35 U.S.C. §112; and Claims 1, 3 and 5-14 are rejected under 35 U.S.C. §103(a). In response, Claims 1 and 11 have been amended, and Claim 12 has been canceled. The amendments do not add new matter. In view of the amendments and for at least the reasons provided below, Applicants respectfully request that the rejections be reconsidered and withdrawn.

In the Office Action, Claims 11-12 are rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. Specifically, the Patent Office alleges that Applicants' specification does not support drying the micro-organisms twice. Applicants have amended Claim 11 to recite, in part, drying the preparation to form particles having an Aw below 0.3 using a drying technique selected from the group consisting of spray drying, fluidized-bed drying, and combinations thereof, compacting the particles under pressure to obtain uncoated pellets comprising a volume of at least 0.02 cm^3, and coating the uncoated pellets with a moisture barrier in an amount of 8% to 18% by weight of the uncoated pellet.

The specification discusses the multitude of variations in steps of preparing the presently claimed pellets. For example, the specification teaches that particles are obtained by mixing the micro-organisms with the inert carbohydrates. Once the particles have been obtained, the specification clearly describes how the particles are dried, compacted and coated as recited by Claim 11. See specification, Abstract; page 3, line 35-page 4, line 3; page 9, lines 1-10; page 12, lines 10-14; page 17, line 10-page 18, line 5. Applicants have also amended independent Claims 1 and 11 to remove the term "about" and cite that the percentage of the coating is based on a weight percentage. The specification teaches at page 7, line 11, that percentages are given in percent by weight unless otherwise indicated. Based on at least these noted reasons, Applicants

believe that the pending claims fully comply with the requirements of 35 U.S.C. §112, first paragraph.

In the Office Action, Claims 1, 3 and 5-14 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite. Applicants have amended Claims 1 and 11 to clarify the scope of the claims. Applicants further submit that the phrase "the inner matrix contains the at least one carbohydrate in an amount from 40% to 70% by weight of total dry matter of the inner matrix" is clearly understood by the skilled artisan. For example, when evaluating all of the dry materials of the inner matrix, the one or more carbohydrates is in an amount ranging from 40% to 70% by weight of these dry materials. Based on at least these noted reasons, Applicants believe that the pending claims fully comply with the requirements of 35 U.S.C. §112, second paragraph.

Accordingly, Applicants respectfully request that the rejections of the claims under 35 U.S.C. §112, first and second paragraphs, be reconsidered and withdrawn.

In the Office Action, Claims 1, 3 and 5-14 are rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,480,641 to Casas-Perez ("*Casas*") in view of EP 0 298 605 to Klapwijk, et al. ("*Klapwijk*") and WO 99/48372 to Van Lengerich ("*Van Lengerich*"). Applicants respectfully traverse the rejection for at least the reasons set forth below.

Independent Claim 1 recites, in part, a pellet comprising a compacted inner matrix and at least one coating, wherein the inner matrix comprises particles comprising at least one inert carbohydrate embedded with 10^5 to 10^8 viable micro-encapsulated micro-organisms per gram of pellet. The amendment is supported in the specification, for example, at paragraphs 134-136 of U.S. Patent Publication No. 2005/0153018. The inner matrix contains the at least one carbohydrate in an amount from 40% to 70% by weight of total dry matter of the inner matrix. The coating comprises a moisture barrier in an amount of about 8% to about 18% of the compacted inner matrix.

Independent Claim 11 recites, in part, a process comprising mixing a preparation of micro-encapsulated micro-organisms and at least one carbohydrate selected from the group consisting of maltodextrins, starches, low molecular weight sugars, hydrocolloids and combinations thereof, wherein the micro-organisms are embedded in the at least one carbohydrate, and drying the preparation to form particles having an Aw below 0.3. The at least one carbohydrate is in an amount ranging from 40% to 70% by weight of total dry matter of the

particles. The particles are compact under pressure to obtain uncoated compacted inner matrix comprising a volume of at least 0.02 cm^3. Finally, the uncoated compacted inner matrix are coated with a moisture barrier in an amount of 8% to 18% of the uncoated compacted inner matrix to produce a pellet. In contrast, Applicants respectfully submit that the cited references fail to disclose or suggest each and every element of independent Claims 1 and 11.

"One way for a patent applicant to rebut a prima facie case of obviousness is to make a showing of 'unexpected results,' i.e., to show that the claimed invention exhibits some superior property or advantage that a person of ordinary skill in the relevant art would have found surprising or unexpected." *In re Soni*, 54 F.3d 746, 750 (Fed. Cir. 1995). Applicants have surprisingly found that compacting dried, micro-encapsulated micro-organisms together with a matrix, which may consist of dried food material, and coating the pellets with a food-grade moisture barrier provides an excellent stability over storage time. See specification, Figure 2.

Without wishing to be bound by theory it is postulated that by adding dried micro-organisms to food material or specific food grade ingredients, drying, compacting them to relatively large particles or pellets ($\geq cm^3$), and coating them with a material that serves as a moisture barrier, a high stability of the micro-organisms is reached. This may be so in part because the ratio of volume and surface is much better exploited than in micro-encapsulated or dried probiotics so far known. The compaction and the moisture barrier further support the optimized ratio and allow a storage stability of probiotics in a moisture environment that was so far not achieved.

Applicants have also found that particles comprising micro-organisms and inert carbohydrates are preferred, because the micro-organisms are less susceptible to subsequent compaction and thus better survival obtained. See specification, Examples 1 and 2. For example, Applicants surprisingly found that the claimed compacted pellets performed better than the commercially available micro-capsules alone, especially after a storage time of 20 days. The recovery rate in the commercially available micro-capsule product decreased strongly and constantly, whereas the decrease in recovery of micro-organisms is prominently slower in the pellets according to the claimed invention.

Both embodiments of *Casas* fail to disclose coating a compacted inner matrix comprising micro-encapsulated micro-organisms and at least one carbohydrate with a moisture barrier in an

amount of 8% to 18% of the compacted inner matrix as required by independent Claims 1 and 11. Indeed, *Casas* fails to disclose or suggest any coating amounts, let alone the pellet coating amounts of the presently claimed processes. Moreover, *Casas* fails to disclose or suggest compacting a preparation of micro-encapsulated micro-organisms and at least one carbohydrate in the recited amounts of 40% to 70% by weight of total dry matter as required by independent Claim 11. In fact, *Casas* fails to disclose any dry weight percentages of its whey in its compressed pellet. At best, *Casas* suggests 100% dry weight of whey in a pellet of the first embodiment where no other components are present in the pellet (e.g., no micro-organisms embedded in 40% to 70% by weight of total dry matter carbohydrate). The second embodiment, on the other hand, includes *L. reuteri* cells suspended in oil mixed with whey. However, *Casas* fails to teach or suggest any dry weight percentages of the whey in that embodiment.

The "first embodiment" includes pelletized whey particles, not mixed with any micro-organisms, coated by micro-organisms suspended in oil. This embodiment is deficient because it does not teach an inner matrix having both micro-organisms and inert carbohydrates. See *Casas*, column 3, lines 55-61. The "second embodiment" includes a micro-organism-oil suspension mixed with whey, with that mixture compressed into pellets with no coating. This embodiment is deficient because it does not teach a coating. See *Casas*, column 3, line 62-column 3, line 2.

The two embodiments of *Casas* both teach the three specific components of whey, micro-organisms and oil. To read on the present claims, the core of the second embodiment is necessary as it teaches a combination of micro-organisms and whey (carbohydrate) required by the claims. However, the second embodiment uses no coating because every component, including oil, is already contained in the pellet core. The first embodiment, on the other hand, teaches a coating of micro-organisms and oil, but contains such coating only because the pellet core solely contains whey. Therefore, there is no reason or suggestion to combine the pellet core of the second embodiment with the coating of the first embodiment because the core of the second embodiment already contains the micro-organism-oil suspension.

Moreover, the Patent Office cites no support in *Casas* for combining the various elements from the different embodiments. Indeed, at no place in the disclosure does *Casas* ever disclose or suggest that a pellet of whey and *L. reuteri* cells could be coated with an oil suspension of *L. reuteri*. Instead, the Patent Office acknowledges a first embodiment and "the" other

embodiment, which provides for only two possible embodiments. Further, Applicants submit that if such a combination were possible in *Casas*, the combination would have been disclosed. Additionally, if such a combination were possible, Applicants submit that *Casas* would not have been so deliberate in the distinction between only a "first embodiment" and "second embodiment." See *Casas*, column 3, line 55-column 4, line 2. As such, Applicants respectfully submit that the skilled artisan would have no reason to combine elements from different embodiments of *Casas* to arrive at the claimed invention.

Klapwijk and *Van Lengerich* fail to disclose or suggest a coating comprising a moisture barrier in an amount of 8% to 18% on a compacted inner matrix having micro-encapsulated micro-organisms and at least one carbohydrate as required by independent Claim 1. *Klapwijk* and *Van Lengerich* also fail to disclose or suggest a process comprising coating the uncoated compacted inner matrix having micro-encapsulated micro-organisms and at least one carbohydrate with a moisture barrier in an amount of 8% to 18% of the uncoated compacted inner matrix as required by independent Claim 11. In addition, *Klapwijk* and *Van Lengerich* fail to disclose or suggest compacting a preparation of micro-encapsulated micro-organisms and at least one carbohydrate in the recited amounts of 40% to 70% by weight of total dry matter as required by independent Claim 11.

Klapwijk and *Van Lengerich* fail to disclose or suggest any coatings of pellets, let alone the presently claimed amounts of pellet coatings. For example, *Klapwijk* discloses aqueous suspensions of viable microflora that have improved ambient stability and is usable in fermentation. See *Klapwijk*, Abstract. The composition of *Klapwijk*, consisting of a micro-organism slurry and flour, is combined and packaged as a finished product for use generally in bread making and, specifically, for "control of the sourdough fermentation in rye bread baking." See *Klapwijk*, page 3, lines 22-25; lines 57-58; Examples 1 and 2. *Klapwijk* fails to even teach or disclose a pellet composition or process for obtaining a pellet for delivery of a probiotic system wherein the probiotics remain viable for a longer period of time than commercially obtainable preparations of probiotics, as is the aim of the present invention. *Van Lengerich* fails to disclose or suggest any micro-encapsulated micro-organisms. See *Van Lengerich*, Abstract. Therefore, Applicants respectfully submit that *Okonogi, Klapwijk* and *Van Lengerich* fail to disclose or suggest each and every element of the present claims.

Further, the skilled artisan would have no reason to combine the cited references to arrive at the present claims because the cited references are directed to entirely distinguishable inventions. *Van Lengerich* provides a product with a heat-sensitive component in a pleasantly tasting and chewable surrounding matrix. See *Van Lengerich*, Abstract. In contrast, *Klapwijk* is entirely directed to bread making and sourdough fermentation. See *Klapwijk*, page 3, lines 22-25; lines 57-58; Examples 1 and 2. Accordingly, because the cited references are directed to entirely distinguishable technology, the skilled artisan would have no reason to combine the cited references to arrive at the presently claims compositions and processes for making same.

What the Patent Office has done is to rely on hindsight reconstruction of the claimed invention. Applicants respectfully submit that it is only with a hindsight reconstruction of Applicants' claimed invention that the Patent Office is able to even attempt to piece together the teachings of the prior art so that the claimed invention is allegedly rendered obvious. Instead, the claims must be viewed as a whole as defined by the claimed invention and not dissected into discrete elements to be analyzed in isolation. *W.L. Gore & Assoc., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1548, 220 USPQ 303, 309 (Fed. Cir. 1983); *In re Ochiai*, 71 F.3d 1565, 1572, 37 USPQ2d 1127, 1133 (Fed. Cir. 1995). One should not use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention. *In re Fine*, 837 F.2d at 1075. (Fed. Cir. 1988).

In sum, Applicants respectfully submit that the cited references fail to disclose or suggest each and every element of independent Claims 1 and 11, along with any of the claims that depend from Claims 1 and 11. Moreover, the cited references fail to recognize the advantages and benefits of the coated pellets having micro-organisms and carbohydrates in accordance with the present claims. Accordingly, Applicants respectfully request that the obviousness rejection of Claims 1, 3 and 5-14 be reconsidered and withdrawn.

For the foregoing reasons, Applicants respectfully request reconsideration of the above-identified patent application and earnestly solicit an early allowance of same. In the event there remains any impediment to allowance of the claims that could be clarified in a telephonic

interview, the Examiner is respectfully requested to initiate such an interview with the undersigned.

Respectfully submitted,

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